

## **REMARKS**

### **The Amendments**

The Specification has been amended to correct typographical and clerical errors.

Claim 4 has been amended for better antecedent basis.

Claim 6 has been amended for proper Markush form.

Claim 7 has been amended to clarify that there can be more than one functional group. Support is found, e.g., in claim 1 and throughout the specification, such as at page 4, line 25.

Claim 53 has been amended to correct a clerical error.

### **The Rejections under Section 102(b)**

Claims 1-3, 5, 9, 10, 13, 27-29, 33, 38, and 39 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Koontz (US 6,022,902). The Office Action states:

Patent '902 discloses gas plasma treatment of microporous membranes in any shape by a gas mixture including an inert gas, e.g argon, and a gas providing functional amino groups on the membrane (functional groups), e.g. ammonia (example 3, claims 1-19; abstract, column 2, lines 25-68; column 4, lines 1-30; column 7, lines 16-19, and lines 37-through column 8, line 7). The use of the functionalized membrane in purification of biochemicals is disclosed in the patent (abstract, column 2, lines 19-23). As to claims 2- 3, microporous membranes with pore size of 1-2000 microns (column 23, claims 8-9, column 6, third paragraph, column 7, second paragraph).

Regarding claim 5; providing the functional groups at the interior and exterior surfaces is also disclosed (column 16, last paragraph). The carrier gases and relative gases are disclosed (see column 7, last paragraph bridging column 8).

The process of making the membrane discussed above results in a membrane having the properties of claims 27-29, and 38. The adsorption properties of claim 33 are inherent of the functionalized membrane containing the amino groups, as discussed above. As to claim 39, the carrier gases as discussed above in the discussion of claim 9.

This rejection is respectfully traversed. All the claims are ultimately dependent on claim 1, and all are limited to preparation of microporous affinity membranes having **regioselective** affinity for compounds in blood or other biologically active fluids. This means there are more functional groups in one region than another of the surfaces of the membrane, i.e., there is "decreasing chemical modification density of the pore walls from the plasma zone area into the membrane structure." (Specification, page 12, lines 27-30. See also, specification, page 11, lines 9-16, which states:)

During the gas plasma treatment this mixture of modifying gas and carrier gas includes the activated species described above and provides the **regioselective** introduction of the amino groups on the surfaces of interest, however, not on the blood side of the microporous affinity membrane substrate, due to deactivation of activated species on the way from the plasma glow discharge zone to the blood side.

In contrast, the Koontz reference teaches a porous article wherein "**essentially the same functional group concentration present throughout the entire interstitial surface of the porous solid,**" so that there is the same functional group concentration in the exterior pore surfaces as the internal pore surfaces. (Col. 3, lines 22-29.) At col. 11, lines 22-36, the Koontz reference describes how the process provides a "uniform dose of reactive gas-phase radicals to the specimen(s)." It defines a "uniform dose" as one that achieves a uniform spacing of induced functionality across the surface of the specimen, so that whether there is low or high levels of functionalization, there is a "**uniform distribution of the functionality across the surface.**" Thus it is clear that the Koontz process is designed to, and does, produce a porous article that is **not regioselective**.

Since the presently-claimed process is designed to produce a regioselective membrane, and does so, as specified in the claims, it is submitted that the Koontz reference does not anticipate the present claims.

### **The Rejection Under Section 103(a)**

Claims 1-7, 9, 10, 13, 14, 15, 22, 26-33, 38, 39, 41, 43, 45, 47, and 49-54 have been rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Williams et al. (US 6,245,537). The Office Action states:

Patent '537 'discloses an affinity membrane having affinity for blood or other biologically active fluids and the process of treating the membrane with gas plasma in the presence of a gas mixture comprising a modifying gas, to provide modifying functional groups onto the membrane surface, as claimed in claim 1 (abstract, column 3, lines 41-62; column 13, lines 2-31; column 7, lines 25-40, column 8, lines 20-48; column 9, lines 53-68; and column 16, lines 56-64).

Patent to Williams et al ('537) fails to teach the membrane as "microporous"; the patent instead produces porous sizes between 80 to 180 microns (column 23, lines 22-28), or between 20 and 200 microns (column 22, line 68-page 23, line 6). Patent '537, however, suggests making the membrane with a desired pore size, e.g. small enough to block out cells and tissue matter (column 12, 13-17), and further teaches controlling the porosity by selecting a leachable material with different particle size, in the process of making the membrane by solvent casting.

One skilled in the pertinent art at the time this invention was made following the suggestions in patent '537 would have been motivated to make membranes of lower pore size to provide a lower degree of retention for a desired intended purpose, by using a leachable material (pore former) with lower particle size.

As to claims 2-3, the patent teaches the flat (film) configuration and a tubular configuration, and the membrane provided on to a support (column 13, lines 10-13; column 23, lines 34-38). Using a support in tubular configuration or hollow fiber would have been obvious to the skilled artisan at the time this invention was made, based on the "tubular" configuration suggested in this patent.

Limitations of claims 4-7 and 9, are further disclosed (column 7, lines 26-55; column 8, lines 20-53; column 9, lines 27-68).

Regarding claim 10, the carrier gas and gases combination is disclosed in this patent (column 9, lines 63-66).

As to claim 13, the treatment includes at least one step treatment, which covers the lower range of "up to 10 cycles".

As to claim 15, the application of plasma treatment is not limited to a particular surface; treating the "polymer" (membrane) is disclosed, which suggests all the surfaces (column 9, last paragraph).

Limitations of claims 27-33 and 38, correspond to resulting modified membrane, discussed above; the peptides and amino groups are disclosed in the references (column 7, lines 28-32; column 8, lines 44-46).

In regard to claim 39, nitrogen is added during the plasma treatment (see column 25, 7-8).

As to claim 43, the term bundle is not disclosed, however, as discussed above membranes with tubular configuration, and provided on a desired configuration support is disclosed; the term "up to 1000 fibers" includes a single fiber.

The membrane thickness, claim 45, is further disclosed in the patent above (column 13, lines 9-10).

As to claim 47, the device is an inherent detecting device, since compounds from blood are attached to the functional groups provided on the membrane material or porous functionalized materials.

As to claims 51-54, the reaction between the blood or biological fluids with the functionalized porous material is discussed above.

As to claims 14, 22, 26, and 41, providing the membrane into a housing for performing the gas plasma treatment is not disclosed in the reference. One skilled in the art at the time this invention was made can predict that functionalization, by gas plasma, as disclosed in this patent, can be expected when contacting the membrane surface with the mixture of gases under the conditions disclosed in patent '537, independently of whether the membrane is provided within a housing or e.g. on a supporting frame or other structure that allows the surface to be in contact with the gas reacting mixture.

This rejection is respectfully traversed. It is noted that this reference fails to disclose or suggest a **regioselective** membrane. Nor does it teach or suggest any process for

making a regioselective membrane. As discussed above, all claims hereof are limited to regioselective microporous membranes.

Although the reference does disclose at col. 3, lines 19-31 that in preparing porous membranes, the "porosity may be controlled **somewhat** by selecting leachable materials with different particle sizes," [emphasis added], it does not teach or suggest that the process can be used to make membranes of the pore size claimed herein.

### **Allowable Subject Matter**

The Examiner is thanked for identifying allowable subject matter in claims 8, 11, 12, 16-21, 23-25, 40, 42, 44, and 46. However, in view of the remarks set forth above, it is believed that all claims are allowable. Therefore none of these claims have been rewritten in independent form to incorporate all the limitations of the claims on which they depend.

### **Conclusion**

This application appearing to be in condition for allowance, passage to issuance is respectfully requested. This Response is accompanied by a Request for Extension of Time (one month) together with the appropriate fee of \$120. If this is incorrect, deduct the correct fee, and any fee required for any extension of time needed from deposit account 07-1969.

Respectfully submitted,

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